FEB 1 2 2002

Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date: Aug 31, 2001

1. Company making the submission:

	Company making submission:	or	Correspondent (contract):
Name:	**Koven Technology, Inc.**		Delphi Consulting Group
Address:	12125 Woodcrest Executive Dr. Suite 220 St. Louis, MO 63141		11874 South Evelyn Circle Houston, Texas 770713404
Telephone:	1-314-542-2101 1-314-542-6020 Fax info@koven.com		1-713-723-4080 1-208-694-6953 Fax harvey@delphiconsulting.com
Contact:	Paul G. Koven President		J. Harvey Knauss Consultant

2. Device

Proprietary Name:	Bi-Directional Doppler Volume Flowmeter Model DVM-4300T.
Common Name:	Bi-Directional Doppler Volume Flowmeter and transcranial Doppler with PPG and PV plug in modules.
Classification Name:	Blood Flowmeter, Cardiovascular

3. Predicate Device:

Modification of the Bi-Directional Blood-flow Velocity and Volume Meter, DVM-4200, Koven Technology, Inc., (Hadeco) K892707 and Transpect Transcranial Doppler, K872292, Medasonics, Inc.

4. Classifications Names & Citations:

21 CFR 870.2100 Cardiovascular Blood Flowmeter

5. Description:

The DVM-4300T pulsed wave Doppler is designed to obtain a blood flow velocity wave through Ultrasound. The ultrasound is transmitted from probe to patient body and moves straight through biophysical objects and is reflected by the moving object (blood flow). The reflected ultrasound is received by the probe and is converted into electrical signals. The incoming Doppler-shifted signals are amplified and go through the Velocity Circuits to remove unnecessary signals and to provide a bi-directional readout. This phase-shifting technique, known as a McLeod circuit, is a standard method employed in direction seeking Doppler devices for several decades. It continues in wide use today.

The detected flow signals are applied to the frequency analyzer for the maximum and mean power spectrum waveforms. The waveform data are applied to the CPU for all the digital processing on LCD Display, operating keys and printer. The audio signal is taken off for the routing to the speaker and headset to generate the analogue signals before digital processing.

The PPG sensor, contains an infrared LED as the light transmitting element and a photosensitive transistor as the receiving element. Soft tissue absorbs light; blood iron constituents reflect light of the amount of blood in the area immediately beneath the sensor.

In Pulse Volume a pressure sensor measures the change in blood content in a limb segment during the cardiac cycle by determining the increase or decrease in the total volume of what segment. A cuff of appropriate dimensions is applied about the limb. Measurement is possible due to the inflow and outflow of blood during the cardiac cycle from the pressure exerted against the cuff.

The large LCD display can display combined bi-directional or directionally separated waveforms and FFT mode. The printer is real time in operation with print out of velocity, flow, heart rate, and probe data.

Integrated stereo speakers provide true Doppler sounds. Headphones may also be used. Use of headphones cancels built in speakers.

6. Indications for use:

Bidirectional lower & upper extremity studies, peripheral vascular procedures, segmental blood pressure studies, and venous patency study with compression maneuvers, penile systolic pressures, digit waveforms and systolic pressures, flow velocities and systolic pressures. Extracranial artery examinations and peak & mean blood velocity determinations. Intraoperative blood flow detection in vascular, cardiovascular and neurovascular applications.

7. Contra-indications:

None known at this time.

8. Comparison:

The Model DVM-4300T has the same device characteristics as the predicate device. Materials and design concept are similar. .

9. Test Data:

The Model DVM-4300T device has been subjected to extensive safety, performance, and validations prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies to applicable industry and safety standards.

The DVM-4300T device labeling includes instructions for safe and effective use. It includes Warning, Cautions, and guidance for use.

10. Literature Review:

A review of literature pertaining to the safety of Doppler Blood Flowmeters has been conducted. Appropriate safeguards have been incorporated in the design of the DVM-4300T.

11. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, Koven Technology, Inc., concludes that the DVM 4300T Blood Volume Flowmeter is safe and effective and substantially equivalent to predicate devices as described herein.

12. Koven Technology, Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.

13. The following pages 5 through 11 contain the Track 1 Summary Tables, and Diagnostic Ultrasound Indications for Use Forms. Note: all probes except the 2 Mhz TDC probe (this submission) have receive FDA Release to Market at earlier dates.

Transducer (Probe): 2 MHz TDC (this submission) new
8 MHz (K892707)
10 MHz (K892707)
10 MHz Bayonet (K935995)

Track 1 Summary Table

Operating Mode(s)								
Clinical Application	A	B	M	PWD	CWD	CD	Combined (Specify)	Other†
Ophthalmic								
Fetal Imaging & Other*				X				
Cardiac, Adult & Pediatric								
Peripheral Vessel								

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color Velocity imaging.

Transducer (Probe): 4 MHz (K892707)
5 MHz (K892702)

Track 1 Summary Table

Operating Mode(s)								
Clinical Application	A	B	M	PWD	CWD	CD	Combined (Specify)	Other†
Ophthalmic								
Fetal Imaging & Other*								
Cardiac, Adult & Pediatric								
Peripheral Vessel					X			

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color Velocity imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Koven Technology, Inc.
c/o Mr. J. Harvey Knauss
Contract Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071-3404

Re: K010452
Trade Name: Bi-Directional Doppler Volume Flowmeter, Model DVM-4300T
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW, FIT
Dated: January 7, 2002
Received: January 8, 2002

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Bi-Directional Doppler Volume Flowmeter, as described in your premarket notification:

Model DVM-4300T

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Kachi Enyinna at (301) 443-8262.

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form

Transducer (Probe): **2 MHz TCD**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				N						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Additional comments:

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices

510(k) Number K010452

Diagnostic Ultrasound Indications for Use Form

Transducer (Probe): **4 MHz Probe**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Additional comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010452

Diagnostic Ultrasound Indications for Use Form

Transducer (Probe): **8 MHz Probe**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				P						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Additional comments: Intraoperative (Vascular) - P

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010452

Diagnostic Ultrasound Indications for Use Form

Transducer (Probe): **10 MHz Probe**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				P						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Additional comments: Intraoperative (Vascular) - P)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K010452

Diagnostic Ultrasound Indications for Use Form

Transducer (Probe): 10 MHz Bayonet

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				P						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Additional comments: Intraoperative (Vascular) - P)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K080452